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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

HH

Office Action Summary	Application No.	Applicant(s)	
	10/823,468	ALTMAN, SANFORD D.	
	Examiner	Art Unit	
	Leslie R. Deak	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 May 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 January 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 31 May 2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1, 3-5, 11-14, 20-25, 28-34, and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki.

In the specification and figures, Zawacki discloses the apparatus substantially as claimed by applicant. With regard to claim 1, Zawacki discloses a dual-lumen catheter 10 with an inner lumen 30 in coaxial relationship with an outer lumen 20, wherein each lumen is formed by an independent tube with an inner surface, outer surface, distal end, and proximal end (see column 1, lines 50-55, column 3, lines 24-45, FIG 1). Both inner lumen 30 and outer lumen 20 have open ends 38, 28 to allow fluid passage,

corresponding to applicant's claimed apertures. Zawacki illustrates that the inner lumen is slideable and may extend beyond the distal end of the outer lumen (see FIGS 1-3). Zawacki further discloses that in certain situations, the inner lumen may be used as an arterial lumen while the outer lumen is used as the venous lumen, meeting the limitations of the claim (see column 4, lines 5-18, column 6, lines 5-24). With regard to applicant's recitation of the length of the lumens, Zawacki discloses that the inner lumen is slideable, meaning that the arterial lumen is capable of being disposed along the entire length of the venous lumen to the hub (see FIGS 2 and 3), meeting the limitations of the claim.

Zawacki fails to disclose or illustrate that the lumens retain a coaxial configuration along the entire length of the catheter. However, Zawacki's disclosure that the lumens are arranged in a coaxial configuration over at least a portion of their length reasonably suggests the desireability of a coaxial configuration to one of ordinary skill in the art. Accordingly, since Zawacki teaches a catheter satisfying the structural limitations claimed by applicant and suggests the shape claimed by applicant, it would have been obvious to one having ordinary skill in the art at the time of invention to form the catheter in the total coaxial configuration claimed by applicant, since Zawacki suggests that such a shape is desireable.

In the specification and figures, Zawacki fails to disclose the length of extension of the inner lumen of the catheter with respect to the end of the outer lumen. With regard to claims 3-5, 12-14, 21-23, Zawacki discloses that the inner lumen 30 of catheter 10 is slideable, or adjustable with respect to the distal end of the outer lumen

20 (see column 4, lines 1-18, FIGS 2, 3). Zawacki teaches that the ability to alter the position of the distal end of the inner tube with respect to the outer tube is especially useful in order to relieve blockages in flow. Zawacki's disclosure suggests that the catheter 10 and its lumens 20, 30, are capable of being deployed at the distances claimed by applicant in order to provide for efficient fluid movement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to deploy the catheter disclosed by Zawacki with the distal ends of the lumens separated by the distance claimed by applicant, in order to provide flexibility in blockage alleviation, as taught by Zawacki.

With regard to claims 11 and 20, Zawacki discloses that the catheter lumens may comprise a circle-C or double-D configuration (see column 4, lines 45-48).

With regard to claims 24 and 25, Zawacki illustrates that both the inner and outer lumens, 30, 20/24, comprise a plurality of circular apertures 36, 26 (see FIG 1).

With regard to claim 27, Zawacki discloses that the catheter may be made of thermoplastics such as PTFE (see column 3, lines 24-33).

With regard to claim 28, Zawacki discloses that reinforcing substances to reduce kinking may be used in the construction of the catheter, including wire (which is a metal formed as a flexible thread), which meets applicant's claim drawn to a metal (see column 4, lines 34-38).

With regard to claim 29, Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the

venous lumen or arterial lumen, depending on the operation of the catheter see column 4, lines 5-18)—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 30, applicant claims the intended placement of the catheter in a patient's vasculature. Such limitations are considered by the examiner to be a statement of the intended use of the catheter. It has been held that a recitation with respect to the manner in which a claimed is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. See MPEP 2114. In the instant case, Zawacki specifically discloses that his catheter is designed to be employed in a patient's vasculature at the junction of the right atrium and the vena cava, and that the lumens are adjustable in order to be deployed in the right position (see column 3, lines 10-15, column 1, lines 50-60). Zawacki's disclosure indicates that the claimed catheter is capable of being placed in the location claimed by applicant, thereby meeting the limitations of the claim.

With regard to claim 31, Zawacki discloses the method claimed by applicant. Zawacki discloses providing the claimed catheter, inserting it into a venotomy site (see column 3, lines 7-22, column 9, lines 8-10), and using the catheter to remove blood, treat the removed blood, and return treated blood to the patient (see column 1, lines 15-20). With regard to applicant's recitation of the length of the lumens, Zawacki discloses that the inner lumen is slideable, meaning that the arterial lumen is capable of being disposed along the entire length of the venous lumen (see FIGS 2 and 3), meeting the limitations of the claim.

With regard to claims 32 and 33, Zawacki discloses the method substantially as claimed by applicant with the exception of deploying the catheter in the claimed location and threading the catheter over a guidewire. However, Zawacki specifically discloses that the catheter may be introduced so that the catheter lies at the junction of the superior vena cava and the right atrium and that the position of the inner and outer lumens may be adjusted to provide for the correct location of the lumens within the vasculature (see column 3, lines 7-67). Therefore, it would have been obvious to place the lumens of the catheter disclosed by Zawacki in the locations claimed by applicant, since Zawacki suggests such positioning and teaches that the catheter is adjustable. With regard to the guidewire, Zawacki discloses that the catheter may be provided with a guidewire, indicating that in some applications, the catheter is deployed over a guidewire into the correct position (see column 3, liens 7-22). Therefore, it would have been obvious to deploy the catheter disclosed by Zawacki over a guidewire as claimed by applicant, since Zawacki teaches that the catheter may be supplied with a guidewire for deployment.

With regard to claim 34, Zawacki discloses that the catheter assembly 10 comprises a hollow hub 40 that connects to the assembly (see FIG 1, column 3, lines 48-67). Zawacki further discloses that the inner lumen—which may act as either the venous lumen or arterial lumen, depending on the operation of the catheter (see column 4, lines 5-18)—is removable and replaceable (see column 1, lines 61-67).

With regard to claim 35, Zawacki discloses that the cathether may be inserted into one of the large central veins, which may include a jugular or subclavian vein (see column 2 line 65 to column 3, line 22).

4. Claims 6-7, 15-16, and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki in view of US 6,595,966 to Davey et al.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of a tapered distal end of the lumens and a therapeutic agent.

With regard to claims 6-7 and 15-16, Davey discloses a catheter that tapers from proximal end 11 to distal end 15 (see FIG 1A, column 6, lines 37-40). Davey teaches that the design may apply to multilumen catheters and minimizes the pressure drop across the catheter, maximizing flow rate through the catheter and minimizing trauma to the fluid flowing through it (see column 4, lines 43-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the dual-lumen catheter disclosed by Zawacki with lumens tapering towards the distal end as disclosed by Davey in order to maximize fluid flow while minimizing fluid trauma, as taught by Davey.

With regard to claim 26, Davey discloses that a surface of the conduit may be treated with heparin, an anticoagulant, in order to prohibit deposit of materials on the surface of the conduit (see column 2, lines 25-30). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter disclosed by Zawacki with a therapeutic agent such as an

anticoagulant as disclosed by Davey in order to prevent deposit of materials on the surface of the conduit, as taught by Davey.

5. Claims 9, 10, 18, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki in view of US 5,762,631 to Klein.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of ridge spoke attached between the outer and inner lumens. Examiner considers the ridge and the spoke claimed by applicant to be substantially similar, since all the limitations of the claimed spoke are part of the claimed ridge (that is, a ridge may function as a spoke). Klein discloses a coaxial dual-lumen catheter with elongate protrusions 25, 31, that are attached on the inner surface of the outer catheter or the outer surface of the inner catheter, respectively (see FIGS 3A, 3B, column 8, lines 17-24). The ridges or spokes assist in the positioning of the catheters relative to one another after deployment (see column 1, lines 50-55). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the catheter disclosed by Zawacki with the ridges or spokes disclosed by Klein in order to position the catheters relative to one another, as taught by Klein.

6. Claims 8 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,758,836 to Zawacki in view of US 5,683,640 to Miller et al.

In the specification and figures, Zawacki discloses the device substantially as claimed by applicant (see rejection above) with the exception of fusing the inner and outer lumens together.

Zawacki teaches that the slideable lumens of the catheter 10 may be locked into position by a mechanism at the proximal end of the catheter, but does not teach such a locking at the distal end (see column 6, lines 1-60). Miller teaches a dual-lumen coaxial catheter for dialysis that is formed in one single piece in order to provide a smooth surface that reduces clots and a unitary structure that reduces tip breakage (see column 2, lines 33-50). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to fuse the lumens disclosed by Zawacki into a single piece, as disclosed by Miller, in order to provide a smooth surface with reduced tip breakage, as taught by Miller.

Response to Arguments

7. Applicant's arguments filed 31 May 2007 have been entered and fully considered.

8. Applicant's arguments with respect to the rejection of the pending claims under 35 UCS 102 have been considered but are moot in view of the new ground(s) of rejection. However, Examiner addresses some of applicant's arguments that are pertinent to the new grounds of rejection under 35 USC 103.

9. Applicant argues that Zawacki discloses a split tip catheter, not the coaxial catheter claimed by applicant. However, Zawacki teaches that the tubes are coaxial at least along a portion of their length (see column 1, lines 50-55), and in an embodiment, the coaxial tubes 20, 30 do not split from their coaxial form until arrival at hub 40, just as illustrated by applicant in FIG 1. Accordingly, Zawacki suggests the desireability of the

claimed coaxial configuration, rendering the instantly claimed device unpatentable over the Zawacki disclosure.

10. Applicant argues that the Davey reference does not remedy the deficiencies of Zawacki. Examiner respectfully disagrees, asserting that the combination of the Zawacki and the Davey references suggest the device as claimed by applicant.

11. Applicant argues that the ridges disclosed by Klein are distinct from the spokes claimed by applicant. However, there is no indication of such a distinction between the plain meanings of the two terms. Examiner is afforded the broadest reasonable interpretation of the terms in the claims. It is the position of the Examiner that broadly interpreted, "spoke" and "ridge" are equivalent structures, and are not patentably distinct. Accordingly, the broadest reasonable interpretation of the claims renders the invention unpatentable over the prior art.

12. Applicant argues that the Miller reference does not remedy the deficiencies of Zawacki. Examiner respectfully disagrees, asserting that the combination of the Zawacki and the Miller references suggest the device as claimed by applicant.

13. With regard to applicant's arguments drawn to fibrin sheath reduction with the claimed configuration, arguments of counsel canno take the place of factually supported objective evidence. See MPEP 2145. In order to set forth the presence of unexpected results, applicant should submit an affidavit under 37 CFR 1.132 (as explained in MPEP 716.02 and 2145) to provide objective evidence of such results.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie R. Deak whose telephone number is 571-272-4943. The examiner can normally be reached on M-F 7:30-5:00, every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Leslie R. Deak
Patent Examiner
Art Unit 3761
31 July 2007